

Applicants: Orna Mor et al.  
Serial No.: 10/562,177  
Filed: December 22, 2005 as §371 of PCT/IL2004/000565  
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Restriction Requirement:

In the March 27, 2008 Office Action, the Examiner required restriction under 35 U.S.C. §121 of pending claims 36-55 to one of the three allegedly patentably distinct inventions.

- I. Claims 36-46, drawn to a method for the treatment of a fibrosis related pathology in a subject in need of such treatment;
- II. Claims 47-54, drawn to a pharmaceutical composition for the treatment of fibrosis related pathology comprising as an active ingredient an inhibitor which inhibits production of HNOEL-iso polypeptide together with a pharmaceutically acceptable carrier; and
- III. Claim 55, drawn to a method for the treatment of disease selected from osteoarthritis, osteoporosis, other bone disease and cardiovascular disease in a subject in need of such treatment comprising administering to the subject an amount of an inhibitor of HNOEL-iso polypeptide sufficient to effect a substantial inhibition of the HNOEL-iso polypeptide so as to thereby treat the subject.

The Examiner also stated that claims 37-42 and 48-51 are generic to the following patentably distinct species: liver fibrosis, pulmonary fibrosis, cardiac fibrosis, scarring, chronic renal insufficiency, chronic renal failure and glomerulosclerosis. Applicants are to elect a species for examination and identify all claims reading on the elected species.

In response to the restriction requirement, applicants hereby elect, with traverse, to prosecute the invention identified by the Examiner as Group I, claims 36-46. In addition, in response to the species election requirement, applicants hereby elect chronic renal insufficiency as the species. The claims in Group I which read on chronic renal insufficiency are 36, 40, 41, 42 and 44-46. Applicants

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request that claims that read on the non-elected species be reconsidered, if generic claim 1 is found allowable.

Applicants, however, respectfully request that the Examiner reconsider and withdraw the restriction requirement. Under 35 U.S.C. §121, restriction may be required if two or more independent and distinct inventions are claimed in one application. Nevertheless, under M.P.E.P. §803, the Examiner must examine the application on the merits if examination can be made without serious burden, even if the application would include claims to distinct or independent inventions. That is, there are two criteria for a proper requirement for restriction: (1) the invention must be independent and distinct, and (2) there must be a serious burden on the Examiner if restriction is not required.

Applicants respectfully submit that there would not be a serious burden on the Examiner if restriction were not required, because a search of the prior art relevant to the claims of Groups II and III would not impose a serious burden once the prior art relevant to Group I has been identified. Therefore, there would be no serious burden on the Examiner to examine Groups I-III together in the subject application.

In addition, applicants submit that there would not be a serious burden on the Examiner if a species election were not required, because a search of the prior art relevant to Group I would identify fibrosis related diseases including nephropathy, chronic renal insufficiency, chronic renal failure and glomerulosclerosis. Therefore, there would be no serious burden on the Examiner to examine Groups I including species (a)-(d) together in the subject application.

In view of the foregoing, applicants maintain that restriction and species election under 35 U.S.C. §121 is not proper, and respectfully request that the Examiner reconsider and withdraw the requirement for restriction.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned

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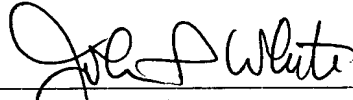
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attorney invites the Examiner to telephone him at the number provided below.

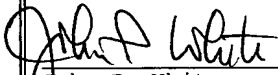
No fee, other than the \$230.00 fee for a two-month extension of time, is deemed necessary in connection with the filing of this Communication. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



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I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

 6/27/06  
John P. White Date  
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